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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,138	08/30/2001	Wallace K. Dyer	04118-0104 (43076-250892)	9300
6980	7590	07/27/2004	EXAMINER	
TROUTMAN SANDERS LLP BANK OF AMERICA PLAZA, SUITE 5200 600 PEACHTREE STREET, NE ATLANTA, GA 30308-2216			EPPERSON, JON D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,138

Applicant(s)

DYER, WALLACE K.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7-11,13,15 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7-11,13 and 20-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>7/15/04</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection (i.e., see 5/17/04 Response). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/3/2004 has been entered. Claims 1, 4, 7-11, 13 and 15-29 were pending. Applicants canceled claim 16 and amended claims 1, 4, 7, 13, 15, 17, 18, 20-23, 28 and 29. Therefore, claims 1, 4, 7-11, 13, 15 and 17-29 are currently pending. An action on the merits follows.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Request for Rejoinder

2. The Examiner acknowledges Applicant's request for rejoinder per MPEP 821.04 (e.g., see 3/3/2004 Response, page 8, last paragraph). However, this provision only takes effect when the product claim is found to be allowable, which is not the case here (e.g., see 35 USC § 102(b) rejection below). Therefore, claims 15 and 17-19 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. In addition, the Examiner notes the following:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable,

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withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Withdrawn Objections/Rejections

3. All outstanding objections and/or rejections are hereby withdrawn in view of Applicant's arguments and/or amendments.

New Rejections

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1, 4, 7-11, 13, and 20-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (US Patent No. 5,336,263) (Date of Patent is **August 9, 1994**) as evidenced by the Polymer Products from Aldrich Reference (of record) (**Please note**: that MPEP 2131.01(d) permits the citation of references or evidence in an anticipation rejection under 35 U.S.C. § 102 in order to show that a characteristic not disclosed in the reference is inherent).

For *claims 1, 4, 7 and 22*, Ersek et al. (see entire document) disclose biphasic compositions for the treatment of urological and gastric fluid disorders (e.g., see abstract), which anticipate claims 1, 4, 7 and 22. For example, Ersek et al. disclose biocompatible micronized textured polyethylene particles having a size greater than sixty microns (e.g., see abstract; see also column 3, lines 23-26, “The textured micro particles have a nominal unidimensional measurement ... between about 80 and 600 microns [i.e., $80 > 60$]”; see also paragraph bridging columns 5-6, “For soft tissue ... [a] desirable material for the textured particles ... [is] polyethylene”). In addition, Ersek et al. disclose various physiological carriers including polyvinylpyrrolidone (e.g., see column 3, lines 37-53, “Examples of appropriate physiologic vehicles [i.e., physiological carriers] are ... polyvinylpyrrolidones”).

For *claims 8-11 and 24-27*, Ersek et al. do not disclose any K values for the polyvinylpyrrolidones (PVP) used therein; however, Ersek et al. disclose a polyvinylpyrrolidone with a molecular weight of 13,700 (e.g., see Example 2), which would inherently possess a K between 13-19 (e.g., see Polymer Products from Aldrich Reference, page 5, Table III, citing “GAF(ISP) Technical Bulletin 2302-203 SM-1290, “PVP polyvinylpyrrolidone Polymers”, wherein the relationship between the K-value and

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the molecular weight and/or intrinsic viscosity of PVP has been calculated and clearly shows that that the K value for the PVP is in the range of 13-19 because 13,700 M_w falls within the $\sim 12,000 M_w$ range). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For **claims 13 and 23**, Ersek et al. disclose an “approximately” 3:2 ratio by weight carrier to particles (e.g., see column 9, lines 25-27, “The mixture utilized was approximately 38% by weight of the polymer particles and 62% of the gel material [i.e., 62% gel / 38% particles = 1.6, which is “approximately” 1.5 or a 3/2 ratio by weight]”; see also paragraph bridging columns 5-6 wherein Ersek et al. disclose that polyethylene can be substituted for poly(dimethylsiloxane) disclosed in Example I; see also column 8, lines 61-63 wherein Ersek et al. disclose that this “ratio” represents a mere design choice).

For **claims 20-21 and 28-29**, Ersek et al. disclose particles having a size greater than 100 microns (e.g., see column 3, lines 23-26, “The textured micro particles have a nominal unidimensional measurement ... between about 80 and 600 microns [i.e., 600 > 100]”).

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
July 15, 2004



ANDREW WANG
SUPERVISORY PATENT EXAMINER
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